

## Remarks

### Preliminary Amendment

Claims 1, 6-9, 14-27, 30-33, and 59-62 are pending and NOT withdrawn after entry of this Amendment. Claims 11, 12, 34-36, 57, and 58 are pending, but withdrawn from consideration in view of the Examiner's Restriction Requirements. Claims 28, 29, 37, and 38 have been canceled in this Amendment (and claims 2-5, 10, 13, and 39-56 were previously canceled). Claims 1, 8, 9, 14, 17-19, 21, 26, 30, and 33 are amended herein. Claim 1 is the only independent claim pending.

No fee for additional claims is believed due, since four claims were canceled and no claims were added.

No new matter is added by the amendments and additions made herein.

Amendments to claims 1, 14, 17-19, 21, 26, and 30 merely substitute the abbreviation "DAP" in place of the longer term "disorder-associated polymorphism." This abbreviation is indicated in claim 1.

Dependence of claim 30 (from claim 57 to claim 1, from which it originally depended) was also adjusted.

Claims 8, 9, and 33 were amended to delete non-elected genes and SNPs therefrom.

### Response to Office Communication

In the Restriction Requirement dated 1 July 2004, the Examiner evidently intended to restrict the invention to assessment of a single polymorphism. However, there is no embodiment of the Applicants' invention that involves assessment of only a single polymorphism. It is therefore impossible for the Applicants to comply with the original Restriction Requirement.

Simply put, the claims requires assessment of two polymorphisms, and do not encompass assessment of only one.

The Applicants understand the Examiner's reluctance to perform a search of the prior art for a large number of individual polymorphisms, and have amended the claims in an attempt to

minimize the Examiner's search requirements while preserving the scope of at least a portion of the Applicants' original invention. In the non-withdrawn claims pending after entry of this Preliminary Amendment and Response, only one particular combination of genes and only one particular combination of polymorphisms is recited. In the following sections, the Applicants briefly summarize the nature of the invention and explain how the claims as amended herein are believed to comply as nearly as possible with the Examiner's Restriction Requirement.

The invention involves assessing at least two "disorder-associated polymorphisms" (DAPs, as defined in paragraph [0026] of the application) in genes in any of ten categories of genes recited in claim 1 as originally filed. In the Restriction Requirement, the Examiner denoted these categories "inventions I to X" and required the Applicants to select a single one. The invention is not limited to a single category - the genes can (and preferably do) include genes in different categories.

In order to limit the searching that the Examiner need do to examine the claims and to comply as nearly as possible with the Restriction Requirement, the Applicants have amended claim 1 (from which all other pending claims depend) to recite a particular combination of the two DAPs recited in the claim. The claims are currently limited to assessment of 1) a DAP in a gene of the category designated VI by the Examiner in the Restriction Requirement and 2) a DAP in a gene of the category designated IX by the Examiner in the Restriction Requirement. Thus, the Applicants have elected a single embodiment of their invention that involves assessment of two particular DAPs.

Within Group VI, the Examiner requires election of one of Groups A-E. The Applicants elect Group A.

Regarding the Examiner's requirement to name a particular gene (i.e., Groups 1-19 in the Restriction Requirement), the non-withdrawn claims as amended herein recite only two genes corresponding to the two elected DAPs - namely a gene encoding a vitamin D receptor (i.e., Group 5) and the gene that encodes interleukin-6 (i.e., Group 12).

Regarding the Examiner's requirement to name a particular polymorphism (i.e., Groups **a-m** in the Restriction Requirement), the non-withdrawn claims as amended herein recite only two SNPs corresponding to the two elected DAPs - namely a vitamin D receptor gene SNP (i.e., Group **b**) and an interleukin-6 gene SNP (i.e., Group **e**).

The Applicants respectfully believe that election of the two embodiments for three of the Groups identified by the Examiner in the Restriction Requirement (i.e., Applicants' election of Groups **VI** and **IX**, Groups **5** and **12**, and Groups **b** and **e**) and further election of Group **A** complies with the Restriction Requirement as nearly as is possible, in that the claims, as filed, recite two DAPs, and the elections made by the Applicants correspond to a single specific combination of the two DAPs.

The Applicants urge the Examiner to appreciate that the invention made and claimed by the Applicants is not merely a specific combination of two specific SNPs, but rather a combination of two or more particular kinds of SNPs. As such, claim 1 should be understood to be a linking claim which encompasses the two particular species of SNPs identified herein as well as other SNPs in the same elected classes. Should the Examiner find claim 1 allowable for the two particular SNPs of Groups **VI** and **IX**, Group **A**, Groups **5** and **12**, and Groups **b** and **e**, the Applicants understand that the Examiner should consider the patentability of claim 1 for all groups linked thereby.

The Examiner is requested to telephone the Applicants' undersigned representative if this Response is considered inappropriate in any way.

**Summary**

The Applicant requests entry of this Preliminary Amendment and early and favorable examination of elected, non-withdraw claims 1, 6-9, 14-27, 30-33, and 59-62, each of which is considered to be consistent with the Applicants' election of Groups VI and IX, Group A, Groups 5 and 12, and Groups b and e herein. In the event that claim 1 is considered allowable for the elected Groups, the Examiner is requested to rejoin and allow claims 11, 12, 34-36, 57, and 58, each of which depends, directly or indirectly from claim 1.

Respectfully submitted,

8 April 2005  
(Date)

By:

  
**GARY D. COLBY, Ph.D., J.D.**

Registration No. 40,961

**Customer No. 08933**

**DUANE MORRIS LLP**

One Liberty Place

Philadelphia, PA 19103-7396

Telephone: 215-979-1000

**Direct Dial: 215-979-1849**

Facsimile: 215-979-1020

E-Mail: [GDColby@DuaneMorris.com](mailto:GDColby@DuaneMorris.com)